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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,609	12/12/2001	Solomon H. Snyder	01107.00171	6957

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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,609	SNYDER ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,9-15,17,18,20,21,23,24,27,28 and 31-38 is/are rejected.

7)☒ Claim(s) 7,8,16,19,22,25,26,29 and 30 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a 371 of PCT/US00/00938 filed January 18, 2000 and published in English as WO 00/43526 on July 27, 2000.

Claims 1-38 are pending.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Currently, the application contains the front page of WO 00/43526 instead of the abstract.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11, 12 (in part), 14, 15, 17, 18, 20(in part), 21, 23(in part), 24, 27 (in part), 28, 31 (in part) and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to or depend from mammalian (claims 1-6, 14, 15, 21, 24, 28, 32-34, 38), murine (claims 9, 35), rat (10, 12, 20, 23, 27, 31, 36) or human (claims 11, 17, 18, 37) serine racemase and a polynucleotide encoding thereof.

The recitation of "mammalian", "murine", rat" or "human" fails to provide a sufficient description of the claimed genus of proteins and encoding polynucleotides as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. A generic statement such as "mammalian serine racemase", etc., without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. The functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

Further, each of the genus of murine, rat or human serine racemases and polynucleotides encoding thereof lacks written description as it merely describes the functional features of the genus without providing any definition of the structural features common to the species within the genus. The claimed genus encompasses not only the single disclosed species (SEQ ID NOs: 1, 8 for murine and SEQ ID NOs: 9,

10 for human) but many other proteins as well since mammalian proteins commonly have allelic and splicing variants which are encoded by the same gene and different genes can encode proteins with the same function. All such allelic and splicing variants as well as all of the murine, rat or human proteins which have serine racemase activity are encompassed by the claims. The specification discloses only one representative species of the claimed genus of murine serine racemase and a polynucleotide encoding thereof (SEQ ID NOs : 8 and 1, respectively) and only one representative species of the claimed genus of human serine racemase and a polynucleotide encoding thereof (SEQ ID NOs : 10 and 9, respectively). Absent a disclosure of the structural features common to the species within the genus, the description of a single species is not sufficient as the description of the entire genus. The functional definition of the genus does not provide any structural information or other identifying characteristics commonly possessed by members of the genus that would allow one to recognize and/or predict a structure of other members of the genus.

The rejection of claims 12, 17, 18 and 20 is based on the highly reasonable assumption that the disclosed partial sequence set forth in SEQ ID NO:6 or 7 (both 27 amino acids, rat) or in SEQ ID NOs: 2 (608 bp, human) or 3 (509 bp, human) does not represent an active fragment. A partial amino acid or nucleotide sequence that does not include a disclosure of any full-length sequence of which it would be a part, would not be representative of the genus of rat serine racemase or a polynucleotide encoding

human serine racemase absent common structural features that impart serine racemase activity.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-6, 9-11, 12 (in part), 13, 14, 15, 17, 18, 20, 21, 23, 24, 27, 28 and 31-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for serine racemase of SEQ ID NOs: 8 or 10 and polynucleotides encoding thereof, including SEQ ID NOs: 1 or 9, does not reasonably provide enablement for serine racemase having an amino acid sequence 85% identical to SEQ ID NOs: 8 or 10 or encoded by a polynucleotide 85% identical to SEQ ID NOs: 1 or 9. The specification does not provide enablement for serine racemase of an undefined structure and a polynucleotide encoding thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of serine racemases and genes encoding thereof broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and amino acid sequence of a single murine (SEQ ID NOs: 1 and 8, respectively) and a single human (SEQ ID NOs: 9 and 10, respectively) serine racemase. Rat serine racemase is identified by the partial amino acid sequences of SEQ ID NOs: 6 and 7 (each 27 amino acids) that constitute a small percent of the full length sequence.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any mutant murine or human serine racemase with 85 % identity to SEQ ID NOs: 8 or 10 or any rat or any mammalian serine racemase with an undisclosed homology to SEQ ID NOs: 8 or 10 or polynucleotides encoding thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting serine racemase activity; (B) the general tolerance of serine racemases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any serine racemase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

beyond that provided, determination of serine racemases and genes encoding thereof is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Allowable Subject Matter

Claims 7, 8, 16, 19, 22, 25, 26, 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,458,576 B1 (Meyers et al., effective filing date February 17, 2000) teach human DNA of SEQ ID NO:1(coding region - SEQ ID NO: 3) that encodes serine racemase of SEQ ID NO:2 (claims 1-8).

SEQ ID NO:1(nucleotides 69-1091) is 100% identical to SEQ ID NO: 9 of the instant invention,

SEQ ID NO:3 is 100% identical to nucleotides 1-1020 of SEQ ID NO:9 and

SEQ ID NO:2 is 100% identical to SEQ ID NO:10 of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

September 29, 2003